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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|-----------------------------|---------------------|------------------|
| 10/781,254 | 02/18/2004 | Joel E. Bernstein | 41959-102742 | 3157 |
| 23644 7590 12/29/2008 BARNES & THORNBURG LLP P.O. BOX 2786 CHICAGO, IL 60690-2786 | | | | |
| EXAMINER KIM, JENNIFER M | | | | |
| ART UNIT 1617 | | PAPER NUMBER | | |
| NOTIFICATION DATE 12/29/2008 | | DELIVERY MODE ELECTRONIC | | |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patent-ch@btlaw.com

**Advisory Action
Before the Filing of an Appeal Brief**

Application No.

10/781,254

Applicant(s)

BERNSTEIN, JOEL E.

Examiner

JENNIFER M. KIM

Art Unit

1617

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 24 September 2008 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☐ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

- a) ☐ The period for reply expires _____ months from the mailing date of the final rejection.
b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.
Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☒ The Notice of Appeal was filed on 11/17/2008. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
(a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
(b) ☐ They raise the issue of new matter (see NOTE below);
(c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
(d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): _____.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
The status of the claim(s) is (or will be) as follows:
Claim(s) allowed: _____.
Claim(s) objected to: _____.
Claim(s) rejected: 1-7, 11 and 12.
Claim(s) withdrawn from consideration: 8-10, 13 and 14.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because:
See Continuation Sheet.
12. ☒ Note the attached Information Disclosure Statement(s). (PTO/SB/08) Paper No(s). 9/24/2008
13. ☐ Other: _____.

/JENNIFER M KIM/
Primary Examiner, Art Unit 1617

Continuation of 11, does NOT place the application in condition for allowance because: The claimed subject matter is deemed to fail to patentably distinguish over the state of the art as represented by the cited references. Applicants argues that the Midha reference merely cites to a publication by Pinder et al. in a sentence in Midha's background that the cis-isomer is more active than the trans isomer and that Midha and U.S. 5,502,047, actually teach away from the instant invention because they suggest that cis-doxepin would have a greater sedative effect, since it is more "active" not a lesser effect as recited in the pending claims. This is not found to be persuasive because it is well known that doxepin hydrochloride is most frequently used to treat the affective disorders depression and also employed less commonly for a treatment of variety of painful and allergic disorders. Although, Midha teaches that cis-isomer is more active than the trans isomer that was disclosed in Pinder et al, it does not change the relevant issue that cis-isomer is more potent than trans-isomer disclosed by Midha as published by Pinder et al. This teaching would motivate one of ordinary skill in the art to formulate preponderance of cis-isomer of doxepin over trans-isomer in order to formulate more potent composition of doxepin for the treatment of disorders that doxepin is most frequently used to treat such as affective disorders depression as well as less commonly for a treatment of variety of painful and allergic disorders. The motivation to combine need not be Applicant's' motivation to invent. In re Dillon 16 USPQ 2d 1897, (Fed. Cir. 1990). Thus, the claims fail to patentably distinguish over the state of the art as represented by the cited references..